

RESPONSE TO OFFICE ACTION

I. Support for Amendments

Specification

The amendment to the paragraph referencing priority applications is made at the suggestion of the Examiner and should not be interpreted to affect the priority claim. This amendment does not introduce any new matter, and is made merely for matters of form.

Claims

Claims 1 and 21 are amended as noted above. These amendments are made to help clarify the language of the claims and are supported throughout the specification, for example at page 4, line 6; and page 7, lines 1 and 14-18. These amendments are made for reasons of proper formatting and for clarity and do not limit the scope of the originally filed claims. These amendments do not constitute new matter.

II. IDS

Applicant acknowledges receipt of the initialed copy of form PTO-1449.

III. Specification Objection

Applicant believes the objection to the specification is rendered moot by the above amendment. This amendment to the specification is made merely for reasons of form and does not alter the scope of the original disclosure.

IV. Claim Objection

Claim 1 stands objected to as alleged to be in improper form. The claim is amended to remove the phrase, "The present invention provides" which should remove the pending objection to the claim.

This claim amendment is made only to remove an inadvertent typographical error and does not limit the scope of the pending claims. This amendment does not constitute new matter.

V. Rejection of Claims under 35 U.S.C. § 101

Claim 1 stands rejected under 35 U.S.C. § 101, alleged to be directed to non-statutory subject matter. More specifically, Claim 1 is alleged as direct to "solely...software wherein there are no limitations that the 'software'...be embodied in a computer-readable medium...".

The amendment to Claim 1 is believed to render this rejection moot. This amendment corrects an inadvertent typographical error and in no way serves to limit the scope of the recited method claim. Accordingly, Applicants respectfully request withdrawal of this rejection.

VI. Rejection of Claims under 35 USC § 112, first paragraph.

Claims 1-21 stand rejected under 35 USC § 112, first paragraph, based on the assertion that the claims are not enabled in view of the disclosure. Specifically, the disclosure is alleged to fail to teach one of skill (a) how to define a reference point of a structure mask; and (b) how to assign a cell identification to such a defined reference point.

Claims 1-21 stand rejected under 35 USC § 112, first paragraph, based on the assertion that they fail to comply with the written description requirement. In particular, the specification is alleged to fail to define both a reference point of a structure mask and assigning a cell identification to individual reference points in a field of view.

The Office acknowledges that both the level of certainty and the level of skill in the art of cell imaging are high.

The Applicants respectfully traverse both bases for rejection.

A. ENABLEMENT

Under 35 U.S.C. § 112, all that is required is that the specification describes the invention in such terms as to enable a person skilled in the art to make and use the invention as claimed. Thus, the specification must teach one skilled in the art how to employ the claimed methods for tracking cells. The test of enablement is whether one reasonably skilled in the art (1) could make and use the invention (2) from the disclosure in the application coupled with information known in the art (3) without undue experimentation. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988); *United States v. Telectronics, Inc.*, 857 F.2d 778 (Fed. Cir. 1988); M.P.E.P. § 2164.01.

The office action states that the invention is not enabled "for a method wherein a reference point is defined for each structure mask of individual cells in a field of view, then a cell identification is assigned to each reference point and used to correlate cells at different time

points because neither the instant specification nor the prior art teach how to do so" (page 4 of the office action, first paragraph).

The office action refers to WO 98/38940 and admits that creating structure masks for object images, such as cell structures, in a field of view is known in the art and teaches that masks may be labeled. The office action further admits that the current specification teaches defining a reference point relative to a cell structure (see page 4, second paragraph). However, the office action asserts that the specification does not teach defining a reference point of each structure mask, or how to assign a cell identification to an assigned reference point anywhere.

The applicants traverse this rejection. The specification (at page 6) makes clear that a structure mask is "**a processed version of the cell structure image** to fill holes...[that can be created by] thresholding the image [of the at least first optically detectable reporter] to select relevant image components with values (position, intensity) **above background outside of the structures of interest.**" Based on this teaching, one of skill in the art would clearly understand that the reference point is being defined relative to a processed version of the cell structure. The office action has pointed to absolutely no basis for its assertion that those of skill in the art can define a reference point relative to a cell structure image, but not relative to a processed version of the cell structure image.

The specification also discloses (bridging pages 5-6) that a reference point, "is a single point defined relative to the cell structure, including but not limited to a center of the cell structure, a center of mass of the cell structure, a centroid (defined as a geometric center) of the cell structure, or by drawing a bounding box around the cell structure, wherein the point can be defined, for example, as the intersection of any two diagonals within the bounding box." Further, the specification teaches how to use the defined reference points in tracking cells (*see*, for example, pg. 7, ln. 14 to pg. 9, ln. 19). Cell identification is discussed at length in the specification, for example from page 7 to page 15, and further by the Examples beginning on page 15, line 11 through page 21, line 26. The teaching found in the specification regarding both how to define a reference point of a cell structure mask, and how to define a cell identification is ample information to enable one of skill to make and use the invention as claimed.

Accordingly, as the specification provides adequate disclosure regarding the definition of a reference point of a structure mask, and how to assign a cell identification to enable one of skill in the art to make and use the entire scope of the claims, Applicants respectfully request reconsideration and withdrawal of this rejection.

B. WRITTEN DESCRIPTION

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 19 U.S.P.Q. 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163(I). There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. M.P.E.P. § 2163(I)(A) (citing *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976)). Thus, a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. *See, e.g., In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971); M.P.E.P. § 2163.04. Therefore, the Office must have a reasonable basis to challenge the adequacy of the written description and has the initial burden of presenting, by a preponderance of the evidence, why a person skilled in the art would not recognize in an Applicant's disclosure a description of the invention defined by the claims. *See, e.g., In re Wertheim*, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976); M.P.E.P. § 2163.04.

Applicant believes that the arguments made above against the enablement rejection also apply to the written description rejection. The specification is clear, particularly at pages 5 and 6, regarding the definition of the term "reference point" as well as how to assign them for use in the method of the invention. The specification also clearly describes assigning a cell identification to individual reference points in a field of view. (citations above).

Accordingly, as the specification clearly demonstrates Applicant's possession of the claimed invention, reconsideration and withdrawal of this rejection is respectfully requested.

VII. Rejection of Claims under 35 USC § 112, second paragraph.

Claims 1-21 stand rejected under 35 U.S.C. § 112, second paragraph, alleged to fail to particularly point out and distinctly claim the invention. Applicant respectfully traverses the rejections.

The rejection of Claim 1 regarding whether the claim is directed to a method or software is believed to be moot, in light of the above amendment to that claim.

The rejection of Claims 1 and 21 over an alleged lack of antecedent basis for the phrase "the first time point" is rendered moot by the amendment to the claims.

The rejection of Claims 1 and 21 over an alleged failure to recite any actual steps for tracking individual cells is rendered moot by the amendment to the claims.

The rejection of Claims 1 and 21 over an alleged lack of a recited "first time point" is rendered moot by the amendment to the claims.

Claims 1 and 21 stand rejected over an alleged failure to define a particular threshold used to create a structure mask. As noted above, the office action admits that creating structure masks for object images, such as cell structures, in a field of view is known in the art. Thus, it is unclear how something can both be known to those in the art and, at the same time, indefinite. The claims are not limited by a specific technique for defining a cell structure mask, since such techniques are known in the art, as acknowledged in the office action. Furthermore, for examples where automatic thresholding is used, the specification clearly states that any automatic thresholding procedure can be used in creating the structure mask, and also describes how thresholding can be used in creating the structure mask:

Images are acquired of the at least first optically detectable reporter molecule, and the images can optionally be preprocessed (shade corrected and smoothed). The images are then thresholded (preferably using an automatic thresholding procedure), producing a structure mask. In a further preferred embodiment, the cell structure is a nucleus, wherein the structure image is a nuclear image, and wherein the structure mask is a nuclear mask. As used herein, the term "mask" means a processed version of the cell structure image to fill holes. Creation of a mask preferably comprises thresholding the image to select relevant image components with values (position, intensity) above background outside of the structures of interest.

Specification, page 6, lines 6-13.

Based on all of the above, the Applicants submit that the those of skill in the art will clearly understand the metes and bounds of the claims, and that the claims particularly point out and distinctly claim the invention. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Claims 1 and 21 stand rejected over an alleged failure to define a structure [sic] point to a structure mask. Applicant assumes that the Examiner intended to mean "reference point" and not structure point. Nevertheless, the specification clearly defines "reference point" and how to determine such reference points within a cell structure (see above). The specification states

"[t]he cell structure reported on by the optically detectable reporter molecule can be any detectable cell structure, including nuclei, intracellular organelles, cytosol markers, and plasma membrane markers. In the simplest case, the cell structure is present as a single entity in the cell, such as the nucleus." (p. 5, ln. 23-26). Thus, there can be one or a plurality of relevant cell structures within an individual cell, which are identified by the reporter molecule(s), and are defined by individual reference points. Therefore, if there exist a plurality of structure masks within a single cell, each structure mask can be given a reference point that is defined relative to the cell structure, "including but not limited to a center of the cell structure, a center of mass of the cell structure, a centroid..., or by a bounding box around the cell structure...". (bridging pp. 5-6).

Thus, the specification is not silent with regard to defining a structure point of a structure mask, and the claim language is precise, clear, and definite. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Conclusion:

If the Examiner believes that a telephone or personal interview would expedite prosecution of the instant application, the Examiner is invited to call the undersigned attorney at (312) 913-2106.

Date:

2/4/04

Respectfully submitted,
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